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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,367	10/30/2001	Barbara A. Brewitt	20371.0004c4	3277

7590 06/27/2006

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,367	BREWITT, BARBARA A.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,9-11 and 13-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *24-28* is/are allowed.

6)☐ Claim(s) *1-3,9-11,13-23 and 29* is/are rejected.

7)☒ Claim(s) *30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the appeal brief filed on 4/13/06. Claims 1-3, 9-11 and 13-30 are pending and are examined. Claims 24-28 are allowed. Claims 1, 41, 46 and 66-73 have been amended. Therefore, claims 1, 3-5, 41, 46 and 66-73 are currently pending and are examined.

2. The finality of the Office Action mailed 6/13/2005 is withdrawn to include missing claim numbers in the relevant rejections.

3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

4. Claim 30 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102(b) maintained

5. The rejection of claims 1, 3, 9, 10,14 and 29 under 35 USC § 102(b) as being anticipated over Antoniades et al. is maintained for reasons set forth in the Office Actions dated 8/24/04 and 6/13/05.

Applicant on page 10 of the brief summaries the teaching of Antoniades et al. Applicant assert that the disclosure and teachings of Antoniades et al. are directed, exclusively, to the treatment of external wounds, e-g. bed sores and burns, with combination compositions. Applicant concedes that Antoniades et al. does teach IGF-1 in combination with IL-1 at low concentration. In fact Antoniades et al. teaches 500ng-1 μg IGF-1 (see column 5, line 15). Based on a molecular weight of 7.6 KD (for IGF-1) this

is found to be less than $1x10^{-6}$ M of the instant invention. However, Applicants assert that claim 1 specifies a preparation having a concentration of less than $1x10^{-6}$ M IGF-1 comprising a homeopathic potency (pages 10-11 of the brief). Applicant is asserting that the homeopathic potency is conferred by the special methods of preparation involving serial dilutions and serial successions (claim the product by process). Applicant asserts that there is no teaching or suggestion whatsoever in Antoniades et al. that the compositions are prepared homeopathically to produce homeopathic potencies. It is further asserted that there is no description, either expressly or inherently, of homeopathic potencies, or of serial dilutions and serial successions (see page 11).

However, this is not fond to be persuasive because "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The

fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations.) Likewise homeopathic potency does not distinguish the prior art over the instant invention.

In addition, Applicanant has not provided any evidence to indicate that there is an unobvious difference between the product of prior art and that of the instant invention because composition of IGF-1 containing 500ng-1 μg taught by Antoniades et al. is the same product as IGF-1 composition that is less than $1x10^{-6}$ M. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) (The claims were directed to a zeolite manufactured by

mixing together various inorganic materials in solution and heating the resultant gel to form a crystalline metal silicate essentially free of alkali metal. The prior art described a process of making a zeolite which, after ion exchange to remove alkali metal, appeared to be "essentially free of alkali metal." The court upheld the rejection because the applicant had not come forward with any evidence that the prior art was not "essentially free of alkali metal" and therefore a different and unobvious product.).

Additionally, *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) (The prior art disclosed human nerve growth factor (b-NGF) isolated from human placental tissue. The claim was directed to b-NGF produced through genetic engineering techniques. The factor produced seemed to be substantially the same whether isolated from tissue or produced through genetic engineering. While the applicant questioned the purity of the prior art factor, no concrete evidence of an unobvious difference was presented. The Board stated that the dispositive issue is whether the claimed factor exhibits any unexpected properties compared with the factor disclosed by the prior art. The Board further stated that the applicant should have made some comparison between the two factors to establish unexpected properties since the materials appeared to be identical or only slightly different.).

Further, with respect to Applicants arguments regarding suitable preparation for oral administration, the reference of solid and liquid formulations (see column 2, lines 26-30) in Antoniades et al. does not preclude the use of such. In addition, the reference also teaches the suspension in growth factors in a gel. Thus meeting the

limitation of impregnation on a solid medium. Therefore the rejection of record is maintained.

Claim Rejections - 35 USC § 103(a), maintained,

6. The rejection of claims 1, 13, 15-18 and 21-23 under 35 USC § 103(a) as being unpatentable over Antoniades et al. in view of Vithoulkas is maintained for reasons set forth in the Office Actions dated 8/24/04 and 6/13/05.

Applicant appears to argue the references individually. Applicants also assert there is no motivation to combine the teachings. These arguments are not found to be persuasive. Applicant's arguments with respect to homeopathic potencies (the lack of relevance to the instant invention) have been extensively discussed in paragraph 5. For motivation to combine the teachings, Only a reason, suggestion or motivation need appear in the cited prior art in order to combine references under 35 U.S.C. 103. *Pro Mold Tool Col. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996). In addition, *In re Kerkhoven* (205 USPQ 1069, CCPA 1980) summarizes:

"It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for the same purpose in order to form a combination that is to be used for the very same purpose: the idea of combining them flows logically from their having been individually taught in the prior art."

Additionally, Only a reason, suggestion or motivation need appear in the cited prior art in order to combine references under 35 U.S.C. 103. *Pro Mold Tool Col. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996). Also, Specific statements in the references themselves which would spell out the claimed invention are not necessary to show obviousness, since questions of obviousness

involve not only what references expressly teach, but what they would collectively suggest to one of ordinary skill in the art. See *CTS Corp. v. Electro Materials Corp. of America* 202 USPQ 22 (DC SNY 1979); and *In re Burckel* 201 USPQ 67 (CCPA 1979).

In the instant invention, it is not necessary that the claimed invention be expressly suggested in any one or all of the references to justify combining their teachings; rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller,* 642 F.2d 413, 208 USPQ 871 (CCPA 1981). As previously stated the motivation to use IGF-1 is provided by Antoniades et al. in that they demonstrate that this facilitates the wound healing process (column 5, lines 30-45). There is a reasonable expectation of success because Vithoulkas et al. have described the derivation of potencies for therapeutic purposes. Although, the references do not recite any specific composition for administration, one of skilled in the art can use different compositions to optimize the therapeutic effect. Therefore the rejection of record is maintained.

7. The rejection of claims 1, 2, 11 and 20 under 35 USC § 103(a) as being unpatentable over Antoniades et al. in view of Clark (5, 597, 797) is maintained for reasons set forth in the Office Actions dated 8/24/04 and 6/13/05.

Applicant appears to argue the references individually. Applicants also assert there is no motivation to combine the teachings. These arguments are not found to be persuasive. Applicant's arguments with respect to homeopathic potencies (the lack of relevance to the instant invention) have been extensively discussed in paragraph 5. In

addition, the rationale to combine references has been presented in paragraph 6 above. Therefore the rejection of record is maintained.

8. The rejection of claims 1and 19 under 35 USC § 103(a) as being unpatentable over Antoniades et al. in view of Whitson-Fischman et al. (U.S. Patent No.5, 162, 037) is maintained for reasons set forth in the Office Actions dated 8/24/04 and 6/13/05.

Applicant appears to argue the references individually. Applicants also assert there is no motivation to combine the teachings. These arguments are not found to be persuasive. Applicant's arguments with respect to homeopathic potencies (the lack of relevance to the instant invention) have been extensively discussed in paragraph 5. In addition, the rationale to combine references has been presented in paragraph 6 above. Therefore the rejection of record is maintained.

Conclusion

9. Claims 24-28 are allowed. In addition, Claim 30 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS 06/06

CHRISTINE J. SAOUD
PRIMARY EXAMINER

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